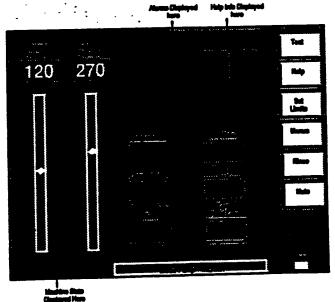
SATRN User Interface (Preliminary)

Definitions

- 1. Dialyze Mode Run the patient
 - All alarms functional.
 - b. Machine has successfully completed self test.
 - c. Air Detector armed.
- 2. Alarm Mode a subset of the dialyze mode that occurs when any parameter goes outside of the preset alarm limits.
 - a. "Alarm" will appear in the bottom left hand corner of the screen.
 - b. The main alarm lamp will light.
 - c. Audio aiarm will sound.
- 3. Rinse Mode Rinse the machine with water, chemical or heat disinfect, introduce conductivity to the machine.
 - a. Dialyzer connectors on Rinse block.
 - b. Air detector disarmed.
 - c. Machine set at preset UF rate. Pressures between flow equalizer cavities is relieved so excessive vacuum does not develop in the flow path.
 - d. Bypass valve cycles into bypass for 5 seconds every minute.
 - e. The Blood pump will run.
 - f. Conductivity or Temperature clarm
 - g. The audio alarm will beep 3 times when the conductivity comes into limits and the machine enters the standby mode.
 - h. The machine will come out of the rinse mode if any of the interlock conditions are not met.
- 4. Standby Mode Equivalent to the warm rinse mode found in the 480 with the rinse features of the SATRN.
 - a. If conductivity and temperature are within alarm limits the warm rinse mode may be entered by pressing the rinse switch.
 - b. All rinse interlocks are met.
 - c: Machine can pass to dialyze mode by successfully completing a self test and by the reset switch being pressed.
 - d. Machine set at preset UF rate. Pressures between flow equalizer cavities is relieved so excessive vacuum does not develop in the flow path.
- 5. Ready Mode Equivalent to the dialyze mode except the "Start" button has not been activated to start the UF, Variable Na, Variable HCO3 or KT/V programs.
- 6. Main Screen Switch -always takes operator back to the Main Screen.
- 7. Help Switch will open a window above the temperature and UF rate displays which provides help information t the operator.

- 8.. ETD Display this will display the estimated time of dialysis.
- RTD Display After the "Start" switch has been pressed and dialysis has started the ETD display will change to the remaining time of dialysis display.
- 10. Set Limits The set limits switch will allow the operator to set the alarm window around the arterial, venous, and conductivity values.
 - a. Conductivity limits will be fixed at a physiological safe range, the set limit switch will only bring the conductivity limit closer to the displayed conductivity value if it is within this safe range.
 - b. Venous low alarm limit will be at 0 mmHg and the alarm limit window will not go below this pressure.
 - c. Both arterial and venous alarm limits will be set at the same time. A window will be set ± 40 mmHg from the displayed pressure, except in the case of point b.
- 11. Menus Switch This switch will allow the operator to go to the Menus screen which can enable the operator to go on to the program or SND screens.
- 12. Rinse Switch enables the operator to go into rinse provided that the safety interlock conditions are met. If rinse is possible the operator will go to the rinse screen where the heat clean and chemical disinfect options are available.
- 13. Dedicated switches which are not on the CRT include:
 - a. On/Off switch this switch allows the machine to be turned on for operation. It does not cut off the mains power to the machine.
 - b. Blood Pump on/off switch will turn on power to the blood pump.



 Manual Bypass switch - will divert the dialysate from the dialyzer to hook up the artificial kidney.

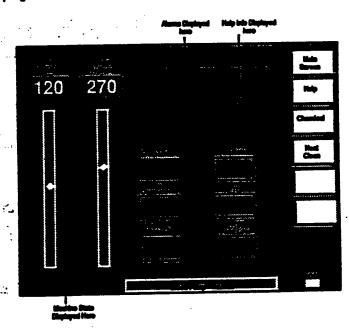
d. Reset switch - allows the operator to reset extracorporeal alarms when the condition is corrected.

Operation

Start Up

- 1. Press the on/off switch.
- 2. If a power failure had just occurred press reset once to go back into dialyze at the previous program.
- 3. To go into rinse, press the rinse switch once. If the rinse interlocks are met, the machine will go to the rinse screen, be in rinse mode and rinse will be displayed in the machine state window below the arterial and venous pressures.

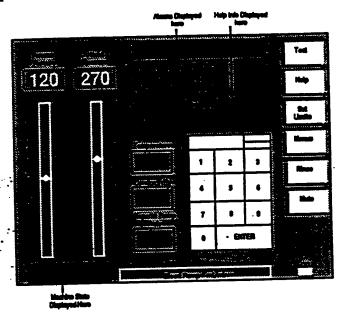
Note To go back to the main screen at any time press the "Main Screen" switch in the top right hand corner of all screens except the main screen.



- 4. If the rinse interlocks are not met, the alarm window will display a message telling the operator that the rinse interlocks are not met.
- 5. Adjust the dialysate flow:
 Press the Qd window. Each time it is pressed it will cycle
 through the available dialysate flow rates. If the value
 displayed in the window is allowed to remain more than

5 seconds the dialysate flow will be controlled to that valu.

6. Adjust the dialysate temperature: The temperature will com up at the previous dialysis set point. If another dialysate temperature is required: Press the temperature window. The calculator will appear at the side of the screen. Use the calculator keypad to input the desired dialysate temperature between 35.5 and 39. Temperatures outside of this temperature range will not change the set point. After the desired temperature appears in the calculator window, press the enter switch.



- 7. The operator should allow the machine to rinse for the appropriate amount of time and then check for residual disinfectant if the machine was recently disinfected.
- 8. After the residual disinfectant is rinsed from the machine, concentrate can be hooked up to the concentrate lines.

If programmed QD, Na, HCQ3 or KT/V is desired, these values can be Note programmed during the rinse mode.

- 9. When the conductivity is within the alarm limits the machine will automatically enter the standby mode.
- 10. A sample of the dialysate should be drawn from the machine and the conductivity of the sample checked. If

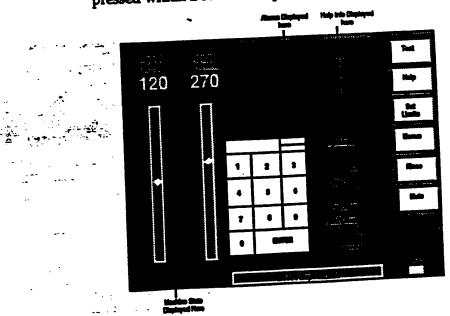
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the conductivity of the sample is correct then the test switch may be pressed and the machine will go into the self test mode. If the test mode is successful the Test Switch will change into th "Start Switch (The machine will shift to the ready mode if the UF has been programmed and the Dialyzer connectors are on the dialyzer).

Basic System Operation

The following procedure details the operator actions to enable the machine to be used for a linear UF removal and standard (non-varied) proportioning. If the Na and the bicarbonate are not going to be varied during the treatment then it is only necessary to set the Ultrafiltration parameters.

- To set UF: 1. Press the ETD display. A calculator keypad will appear. Use the keypad to set the expected time of dialysis in hours and minutes.
- If the incorrect value has been input into the calculator, press the clear key Note and then enter the correct value.
- Setting the ETD will set it in any screen in which it shows. This value does Note not have to be set again once it is set
 - 2. After the correct time in hours and minutes has been pressed in the calculator. Press the enter key.
 - 3. Press the Target fluid loss display. (If the help switch is pressed within 2 seconds of pressing Target Fluid Loss



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switch, the UF worksheet will appear in the help area).

a. If the help switch is not pressed a calculator will appear. Use the keypad to set the desired ultrafiltrate to be removed f r the treatment in liters per hour.

b. If the UF worksheet is used enter each value with the calculator. When the worksheet is completely filled in the final value will be the target fluid loss.

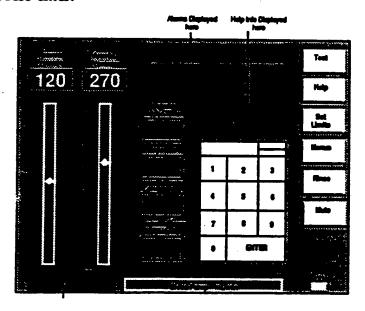
4. After the target fluid loss has been entered, press the enter key.

Note

After the treatment has started if the patient has become hypotensive or it is necessary to go to a low ultrafiltration rate: Press the UF rate display once and the UF rate will go to the preset value of 100 mL/hr and the TMP alarm will delay for a minute and a new limit window will automatically go around the pressures caused by the 100 mL/h UF rate. To leave this minimum UF mode, press the UF rate display again and the machine will return to the previous UF rate and the TMP alarm will delay for a minute and will be set again around the TMP that results from resuming the UF rate.

Set the Heparin Pump Rate

- 1. Press the heparin pump rate display. The calculator will appear and a heparin time display will appear in the help window.
- 2. Enter the desired heparin pump infusion rate.
- 3. Press enter.
- 4. If preprogrammed heparin pump shut off is desired, press the heparin time display enter the heparin time (for instance 3.5 h for a 4 h dialysis).
- 5. Press enter.



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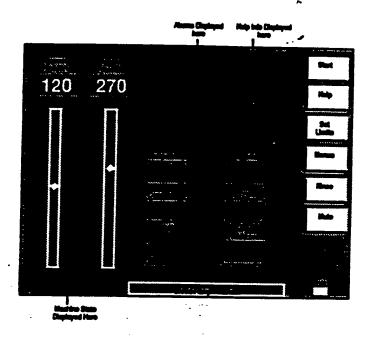
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Dialyzing the Patient

1. After the conductivity has been verified. Return to the main screen if necessary (by pressing Main Screen Switch). Then press the Test Switch. The machine will automatically self test the alarms and functions. If the machine has a problem it will not allow the operator to go further and will report a machine error. If the test is complete and there is no problem the machine state will change to the ready mode and the Test Switch will change to the Start Switch.



- 2. During the ready mode the dialyzer may be primed and the UF rate is = 100 mL/h.
- 3. When the dialyzer is primed, set or make sure the UF and the heparin infusion rate have been set (if Na, KT/V Bicarbonate or UF programming is desired this should be done prior to putting the patient on the machine).
- 4. Hook the patient to the machine. To start the blood pump, press the blood pump switch and then press the desired blood pump flow rate on the touch screen.
- 5. After the patient is hooked to the machine and blood is flowing through the extracorporeal circuit press the Start Switch. This will start the UF mode and any other programmed variables. After = 1 minute the machine will set the limits of the Venous, Arterial and the TMP. It will also close the alarm window around the conductivity

value. The Heparin rate display will change to the TMP display.

If it is necessary to change the heparin infusion rate: touch the TMP display and it will change to the Heparin Rate display. If the Heparin rate display is pressed the calculator will appear, input the new heparin infusion value and press the enter key and the new heparin infusion rate will be set. The heparin display will automatically change back to the TMP display in 2 minutes.

Extracorporeal Alarms

- 1. During an extracorporeal alarm. The UF rate will go to zero, the blood pump will stop and the line clamp will clamp. The machine will not count this time as dialysis time.
- 2. To get out of an extracorporeal alarm the operator must press the Reset Switch. The pressure alarms will be overridden for ~ 5 seconds after reset has been pressed to allow the blood flow rate to return to its previous setting.

Change Pressure Limits

If it is necessary to change the alarm limits of the Venous, Arterial and the TMP. Press the set limits switch. The limits will automatically form a window around the pressure setting.

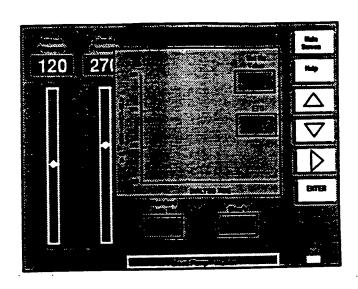
Programming

If it necessary to program NA, HCO3, KT/V or UF during treatment

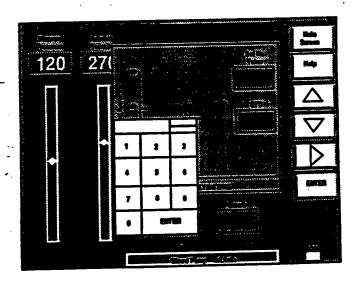
- a. Press "Menus".
- b. When the switches change on the right hand side of the monitor press "Program".
- c. When the switches change on the right hand side of the monitor, press either "Program UF", Program Na, KT/V or Program Bicarb depending on what variable is desired to be programmed.

To set the programmable Sodium:

- 1. Press "Program Na" switch. The program Na graph and switches should appear on part of the display.
- 2. Press the Standard Bath Na switch. The calculator appears. Enter the sodium value displayed on the concentrate container. Press enter. calculator disappears. The sodium value will be displayed in the Standard Bath Na window.

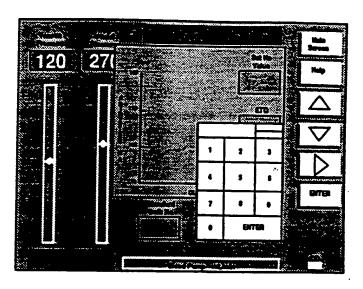


3. If the ETD was not entered previously press the ETD switch. The calculator appears. Enter the dialysis time in hours and minutes. Press enter. calculator disappears. The dialysis time will be displayed in the ETD window.

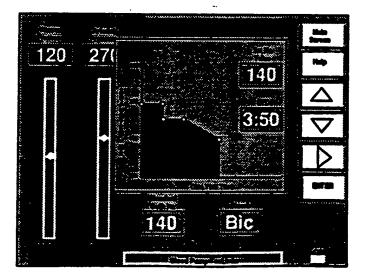


- 4. The Bicarb window-will default to a "Ace" (acetate) position, touch the "Bicarb?" switch to change this to a "Bic" if a bicarbonate dialysis is to be run.
- 5. To set the variable sodium:
 - a. The operator presses the approximate place on the graph of the desired starting sodium value. The actual value entered will be displayed in the Set Na Value window. This value can be fine tuned with the ▲ and ▼ arrow keys.

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- b. Then the operator will press the intersection point (NA/time) on the graph for the next sodium value desired. If the operator would like the sodium to vary in steps, the same sodium value as entered in step 5a should be entered Then the new sodium value should be entered at the same time coordinate on the graph. To view sodium values that have been previously entered use the \$\partial arrow key to cycle through each sodium setting.
- 6. Sodium values should be entered for as many steps (20 minute steps) as desired. It is not required to enter a step for each 20 minute sequence. If 160 were the first point selected and 140 was selected 2 hours later. The machine would vary the sodium of the dialysate slowly lowering it to 140 over the two hours. If 160 was the first value selected and 160 was pressed in the two hour time coordinate, then 140 pressed in the two hour time coordinate. The dialysate sodium value for the first two



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hours would be 160 and would change at the end two hour time frame to 140 where it would remain for the rest of the treatment unless another sodium value was selected. Step 5 should be repeated for all steps that the sodium should be changed to.

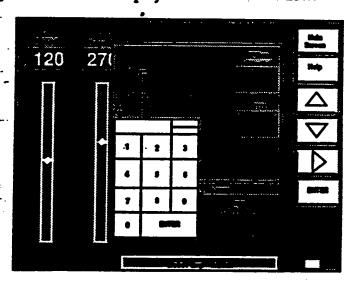
- 7. After all sodium values are entered on the machine, the enter key should be pressed and the program is set in the machine.
- 8. If another program or a program change is desired it can be reinput entirely or any of the values can be adjusted with the arrow keys and reentered.

Note

The \$\psi\$ switch will highlight the area selected. It will move one setting each time the \$\psi\$ switch is pressed. When the \$\psi\$ is pressed after the last value it will roll around back to the first value entered.

To Set the Programmable Ultrafiltration:

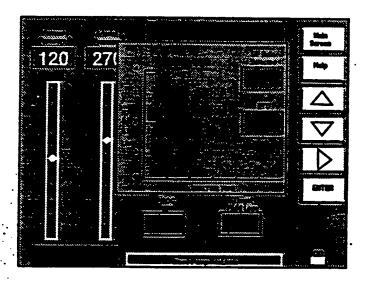
- 1. Press "Program UF" switch. The program UF graph and switches should appear on part of the display
- 2. If the ETD was not entered previously press the ETD switch. The calculator appears. Enter the dialysis time in hours and minutes. Press enter. calculator disappears. The dialysis time will be displayed in the ETD window.



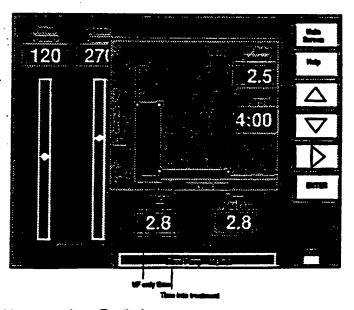
3. If the Target Fluid Loss was previously set the UF goal will appear in the display. If not touch the Target Fluid Loss display. The calculator appears. Enter the Target Fluid Loss in liters per hour. Press enter. The calculator disappears. The Target Fluid Loss will be displayed in the window.

- 5. To program the UF removal:

 a. The operator presses the approximate place n the graph at the desired starting UF rate. The actual value entered will be displayed in the UF Rate Selected wind w. This value can be fine tuned with the ▲ and ▼ arrow keys.
 - b. Then the operator will press the intersection point (UF/time) on the graph for the next Ultrafiltration value desired. If the operator would like the UF to vary in steps, the same UF value as entered in step 5a should be entered Then the new UF value should be entered on the same time coordinate on the graph. To view UF values that have been previously input, use the farrow key to cycle through each UF rate setting.



As the operator sets the UF values in the graph the "Prog UF" display will Note show add each value until the display is equal to the Target Fluid Loss.



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- 6. Ultrafiltration values should be entered for as many steps (20 minute steps) as desired. It is not required to enter a step for each 20 minute sequence. If 1L/h were the first point selected and 0.5L/h was selected 2 hours later. The machin would control the ultrafiltration rate slowly lowering it to 0.5L/h over the two hours. If 1L/h was the first value selected and 1L/h was pressed in the two hour time coordinate, then 0.5L/h pressed in the two hour time coordinate. The ultrafiltration control rate for the first two hours would be 1L/h and would change at the end two hour time frame to 0.5 where it would remain for the rest of the treatment unless 0.5 L/h would exceed the Target UF value. Step 5 should be repeated for all the programmed UF rate changes desired.
- 7. After all UF rate variations are entered on the machine, the enter key should be pressed and the program is set in the machine.
- 8. If another program or a program change is desired it can be reinput entirely or any of the values can be adjusted with the arrow keys and reentered.

. 9. If sequential ultrafiltration is desired:

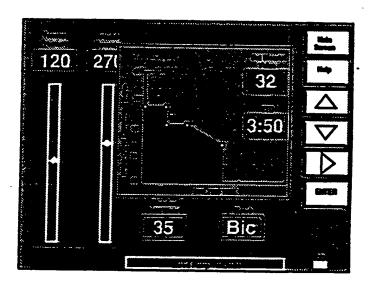
- a. Press the Manual switch once (while the UF program screen is on).
- b. Press the time coordinate on the graph when you would like the machine to go into sequential ultrafiltration.
- c. Press the manual switch once for each 20 minute interval that sequential UF is desired. A bar showing each 20 minute period should appear on the bottom of the UF graph. If the wrong time interval is selected press the manual bypass switch until it reaches the end of the ETD and the entered time value will be cleared and a new one entered.
- d. Press enter when the setting is correct.

To Set the Programmable Bicarbonate:

- 1. Press "Program Bicarb" switch. The program Bicarb graph and switches should appear on part of the display.
- 2. Press the Standard Bath Bicarbonate switch. The calculator appears. Enter the bicarbonate value displayed on the concentrate container. Press enter. The calculator disappears. The bicarbonate value will be displayed in the Standard Bath bicarbonate window.
- 3. If the ETD was not entered previously press the ETD switch. The calculator appears. Enter the dialysis time in hours and minutes. Press enter. calculator disappears. The dialysis time will be displayed in the ETD window.
- 4. To set the variable bicarbonate

- a. The operator presses the approximate place on the graph of the desired starting bicarbonate value. The actual value entered will be displayed in the Set Bicarbonate Value window. This value can be fine tuned with the ▲ and ▼ arrow keys.
- b. Then the perator will press the intersection point (bicarbonate/time) on the graph for the next bicarbonate value desired. If the operator would like the bicarbonate to vary in steps, the same bicarbonate value as entered in step 4a should be entered. Then the new bicarbonate value should be entered at the same time coordinate on the graph.

To view bicarbonate values that have been previously entered use the arrow key to cycle through each bicarbonate setting.



- 5. Bicarbonate values should be entered for as many steps (20 minute steps) as desired. It is not required to enter a step for each 20 minute sequence. If 35 meq/L were the first point selected and 32 was selected 2 hours later. The machine would vary the bicarbonate of the dialysate slowly lowering it to 32 over the two hours. If 35 was the first value selected and 35 was pressed in the two hour time coordinate, then 32 pressed in the two hour time coordinate. The dialysate bicarbonate value for the first two hours would be 35 and would change at the end two hour time frame to 32 where it would remain for the rest of the treatment unless another bicarbonate value was selected. Step 4 should be repeated for all steps that the bicarbonate should be changed to.
- 6. After all bicarbonate values are entered on the machine, the enter key should be pressed and the program is set in the machine.

7. If another program or a program change is desired it can be reinput entirely or any of the values can be adjusted with the arrow keys and reentered.

Kinetic Modeling Program

During this mode the machine will automatically calculate the ETD and will update it as blood flow is changed or extracorporeal alarms interfere with treatment. In addition to calculating the optimum time of dialysis, the kinetic modeling program also displays the variables such as total blood treated.

- 1. Press "KT/V" switch.
- Press the KOA display. Enter the KOA value of the dialyzer. Press the enter switch.
- 3. Press the V switch. Enter the physician calculated body urea distribution. Press the enter key.
- Press the dialysis efficiency switch. Enter the value from
 0.9 to 1.5 (adequacy of dialysis required). Press the enter switch.

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5. The machine will automatically calculate the ETD and put this variable into all the other ETD windows on other screens.

Discontinue Dialysis

- If the UF goal is reached the machine will go to 100mL/h
 UF rate; the RTD display will go to zero and the audio alarm will beep three times.
- 2. Lower the Blood flow rate. The arterial and venous alarms have a two second delay. It will be necessary to the Set Limits Switch a couple of times as these pressures are changed by lowering the blood pump speed.
- 3. Take the patient off the machine.

 (Return extracorporeal blood to the patient, turn off the blood pump, clamp the blood lines and disconnect from the patient.)

Ritise Machine After Dialysis

- 1. Press the manual bypass switch.
- Remove the dialyzer and the blood lines from the machine. Hook the dialyzer connectors to the rinse block.
- 3. Press the Rinse Switch.

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4. After acetate dialysis, connect the acid/acetate concentrate lin to the acid/acetate rinse fitting.

Remove the acid/acetate concentrate line from the acetate concentrate container and connect it to the acid/acetate rinse fitting.

After bicarbonate dialysis, connect the bicarbonate concentrate line to the bicarbonate rinse fitting.

5. After acetate dialysis, rinse the machine with water for 15 minutes.

After bicarbonate dialysis;

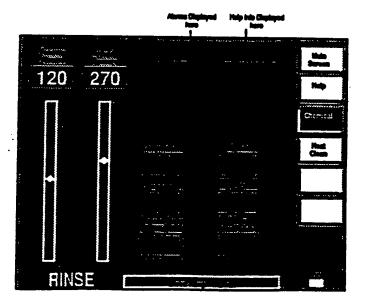
- a. Rinse the machine with acid concentrate and water for 5 minutes.
- b. Connect the acid/acetate concentrate line to the acid/acetate rinse
- c. Rinse the machine with water for at least 10 minutes.

Disinfect the Machine after Dialysis

1. Machine is in the rinse mode and has been rinsing with water at least 15 minutes. If the main screen is showing, press the rinse switch to go to the rinse screen.

Chemical Disinfection

- a. For Chemical disinfect move the chemical disinfect line into a container of 4 to 6% household bleach. Press the Chemical Disinfect Switch. The machine will infuse the bleach for 14 minutes, at the end of 14 minutes the audio alarm will beep 3 times.
- b. The machine will continue rinsing. When the operator places the disinfect line into the disinfect fitting the machine will begin a programmed 10 water rinse.



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. c. After 10 minutes the machine should be checked for residual bleach. If the machine is free of bleach, it can be prepared for the next patient or turned off.

Heat Clean

- a. T heat clean the machine all concentrate lines should be in their appropriate fittings. Press the Heat Clean Switch. The machine will go through the predetermined heat clean cycl (~30 to 45 minutes of heat and then cool down.
- b. At the end of the Heat Clean cycle the machine will return to the rinse mode.